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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/729,034	12/04/2000	Cheryl A. Pederson	56094USA1A.002	4710

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EXAMINER

KALINOWSKI, ALEXANDER G

ART UNIT	PAPER NUMBER
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3626

DATE MAILED: 03/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/729,034

Applicant(s)

PEDERSON ET AL

Examiner

Alexander Kalinowski

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 04 December 2000.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 2.3.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

1. Claims 1-21 are presented for examination.

#### ***Claim Rejections - 35 USC § 101***

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-12 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The basis of this rejection is set forth in a two-prong test of:

- (1) whether the invention is within the technological arts; and
- (2) whether the invention produces a useful, concrete, and tangible result.

For a claimed invention to be statutory, the claimed invention must be within the technological arts. Mere ideas in the abstract (i.e., abstract idea, law of nature, natural phenomena) that do not apply, involve, use, or advance the technological arts fail to promote the "progress of science and the useful arts" (i.e., the physical sciences as opposed to social sciences, for example) and therefore are found to be non-statutory subject matter. For a process claim to pass muster, the recited process must somehow apply, involve, use, or advance the technological arts.

In the present case, the instant claims fail to recite the use of any type of technology (e.g. computer system) within the recited steps of the claimed method of managing occurrence of risk of infection. The recited steps constitute an idea on how to manage surgical site infections.

Mere intended or nominal use of a component, albeit within the technological arts, does not confer statutory subject matter to an otherwise abstract idea if the component does not apply, involve, use, or advance the underlying process.

Additionally, for a claimed invention to be statutory, the claimed invention must produce a useful, concrete, and tangible result. In the present case the claimed method recites steps for managing surgical site infections.

Although the claimed invention produces a useful, concrete and tangible result, since the claimed invention as a whole is not within the technological arts, as explained above, claims 1-12 are deemed to be directed to non statutory subject matter. The Examiner suggests adding language to the body of the claims (i.e. limitations) indicating that the steps are carried out through the use of technology (e.g. computer system).

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mangram et al., 'Guideline for prevention of surgical site infection' (hereinafter Guidelines) in view of Ormond-Walshe, Sarah, "Computerised databases in infection control" (hereinafter Walshe).

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As to claim 1, Guidelines discloses A method for managing the occurrence or risk of surgical site infection incident to a surgical procedure (pages 100-120), the method comprising:

- (a) identifying a plurality of stages of operative care, including at least a preoperative stage, an intraoperative stage, and a postoperative stage (page 98);
- (b) identifying one or more points-of-care within each identified stage of operative care (page 98);
- (c) for each point-of-care, identifying one or a plurality of sources of measurable risk of surgical site infection (page 98);
- (d) for identified surgical site infection risks, identifying at least one practice for either or both managing or reducing the risks, either individually for each risk or collectively for more than one risk (pages 106-116)

Guidelines do not explicitly disclose

- (e) aligning the identified practice or practices within each point-of-care to provide a set of sequential practices throughout each of the stages of operative care (pages 100-120)

Guidelines does not explicitly disclose

Aligning the practices in a manner that provides a desired management of the overall occurrence or risk of surgical site infection.

However, Walshe discloses aligning the practices in a manner that provides a desired management of the overall occurrence or risk of surgical site infection (i.e. establishment of surveillance and control programs was strongly associated with reductions ...)(page 3). It would have been obvious to one of ordinary skill in the art at

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the time of Applicant's invention to include the aforementioned limitation as disclosed by Walshe within Guidelines for the motivation of reducing infection rates (page 3).

As to claim 2, Guidelines discloses The method of claim 1 wherein the preoperative stage of operative care comprises at least the following points-of-care: preoperative assessment, operation scheduling, admissions, operation room entry (page 101).

As to claim 3, Guidelines discloses The method of claim 2 wherein the preoperative assessment point-of-care contains one or more of the following sources of diagnostic testing, laboratory test administration, patient education and instruction, patient risk assessment and management (page 105).

As to claim 4, Guidelines discloses The method of claim 1 wherein the intraoperative stage of operative care comprises at least the following points-of-care: incision and wound closure (pages 110-113).

As to claim 5, Guidelines discloses The method of claim 1 wherein the postoperative stage of operative care comprises at least the following points-of-care: operating room exit and patient follow-up (pages 114-116).

As to claims 6-21, the claims are substantially similar in scope to claims 1-5 and are rejected on the same basis.

### ***Conclusion***

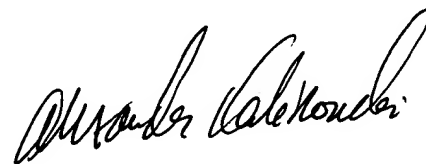
5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

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- a. "An operating surveillance system .." discloses a national surveillance of surgical site infections.
  - b. "Using a CQI process ..." discloses a quality improvement process for antimicrobial use in surgery.
6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander Kalinowski, whose telephone number is (703) 305-2398. The examiner can normally be reached on Monday to Thursday from 9:00 AM to 6:30 PM. In addition, the examiner can be reached on alternate Fridays.

If any attempt to reach the examiner by telephone is unsuccessful, the examiner's supervisor, Joseph Thomas, can be reached on (703) 305-9588. The fax telephone number for this group is (703) 305-7687 (for official communications including After Final communications labeled "Box AF").

Hand delivered responses should be brought to Crystal Park 5, 2451 Crystal Drive, Arlington, VA, 7th Floor, receptionist.



Alexander Kalinowski

Primary Examiner

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3/21/2004